SECOND REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

# HOUSE BILL NO. 1695

## 91ST GENERAL ASSEMBLY

Reported from the Committee on Critical Issues, Consumer Protection and Housing, April 9, 2002, with recommendation that the House Committee Substitute for House Bill No. 1695 Do Pass.

Taken up for Perfection April 18, 2002. Bill ordered Perfected and printed, as amended.

TED WEDEL, Chief Clerk

3419L.03P

## AN ACT

To repeal section 376.1219, RSMo, and to enact in lieu thereof five new sections relating to health insurance coverage for PKU and inherited diseases.

*Be it enacted by the General Assembly of the state of Missouri, as follows:*

Section A. Section 376.1219, RSMo, is repealed and five new sections enacted in lieu thereof, to be known as sections 34.375, 376.429, 376.1219, 376.1221 and 376.1253, to read as follows:

**34.375. 1. This section shall be known and may be cited as the "Missouri Calcium Initiative".**

**2. The purchasing agent for any governmental entity that purchases food or beverages to be processed or served in a building or room owned or operated by such governmental entity shall give preference to foods and beverages that:**

**(1) Contain a higher level of calcium than products of the same type and quality; and**

**(2) Are equal to or lower in price than products of the same type and quality.**

**3. Notwithstanding the provisions of subsection 2 of this section to the contrary, if a state institution determines that a high calcium food or beverage that is preferred pursuant to subsection 2 of this section will interfere with the proper treatment and care of a patient of such institution, the purchasing agent shall not be required to purchase the**

**EXPLANATION — Matter enclosed in bold faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.**

**high calcium food or beverage for such patient.**

**4. The requirements of this section shall be in addition to any requirements placed upon a governmental entity by the United States Department of Agriculture under the National School Lunch Program or the School Breakfast Program.**

**5. For purposes of this section, "governmental entity" means the state of Missouri, its departments, agencies, boards, commissions and institutions, and all school districts of the state. Governmental entity does not include political subdivisions of the state.**

**6. Notwithstanding the provisions of this section to the contrary, a purchasing agent who has entered into a contract with a supplier before July 1, 2002, to purchase food and beverages shall not be required to purchase high calcium foods and beverages if purchasing such products would change the terms of the contract.**

**376.429. 1. All health benefit plans, as defined in section 376.1350, that are delivered, issued for delivery, continued or renewed on or after August 28, 2002, and providing coverage to any resident of this state shall provide coverage for routine patient care costs as defined in subsection 6 of this section incurred as the result of phase II, III, or IV of a clinical trial that is approved by an entity listed in subsection 4 of this section and is undertaken for the purposes of the prevention, early detection, or treatment of cancer.**

**2. In the case of treatment under a clinical trial, the treating facility and personnel must have the expertise and training to provide the treatment and treat a sufficient volume of patients. There must be equal to or superior, noninvestigational treatment alternatives and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be superior to the noninvestigational alternatives.**

**3. Coverage required by this section shall include coverage for routine patient care costs incurred for drugs and devices that have been approved for sale by the Food and Drug Administration (FDA), regardless of whether approved by the FDA for use in treating the patient's particular condition, including coverage for reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial.**

**4. Subsections 1 and 2 of this section requiring coverage for routine patient care costs shall apply to clinical trials that are approved or funded by one of the following entities:**

**(1) One of the National Institutes of Health (NIH);**

**(2) An NIH Cooperative Group or Center as defined in subsection 7 of this section;**

**(3) The FDA in the form of an investigational new drug application;**

**(4) The federal Departments of Veterans' Affairs or Defense;**

**(5) An institutional review board in this state that has an appropriate assurance approved by the Department of Health and Human Services assuring compliance with and implementation of regulations for the protection of human subjects (45 CFR 46); or**

**(6) A qualified research entity that meets the criteria for NIH Center support grant eligibility.**

**5. An entity seeking coverage for treatment, prevention, or early detection in a clinical trial approved by an institutional review board under subdivision (5) of subsection 4 of this section shall maintain and post electronically a list of the clinical trials meeting the requirements of subsections 2 and 3 of this section. This list shall include: the phase for which the clinical trial is approved; the entity approving the trial; whether the trial is for the treatment of cancer or other serious or life threatening disease, and if not cancer, the particular disease; and the number of participants in the trial. If the electronic posting is not practical, the entity seeking coverage shall periodically provide payers and providers in the state with a written list of trials providing the information required in this section.**

**6. As used in this section, the following terms shall mean:**

**(1) "Cooperative group", a formal network of facilities that collaborate on research projects and have an established NIH-approved Peer Review Program operating within the group, including the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;**

**(2) "Multiple project assurance contract", a contract between an institution and the federal Department of Health and Human Services (DHHS) that defines the relationship of the institution to the DHHS and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects;**

**(3) "Routine patient care costs", shall include coverage for reasonable and medically necessary services needed to administer the drug or device under evaluation in the clinical trial. Routine patient care costs include all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial except:**

**(a) The investigational item or service itself;**

**(b) Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and**

**(c) Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.**

**7. For the purpose of this section, providers participating in clinical trials shall obtain a patient's informed consent for participation on the clinical trial in a manner that**

**is consistent with current legal and ethical standards. Such documents shall be made available to the health insurer upon request.**

**8. The provisions of this section shall not apply to a policy, plan or contract paid under Title XVIII or Title XIX of the Social Security Act.**

376.1219. 1. Each policy issued by an entity offering individual and group health insurance which provides coverage on an expense-incurred basis, individual and group health service or indemnity type contracts issued by a nonprofit corporation, individual and group service contracts issued by a health maintenance organization, all self-insured group health arrangements to the extent not preempted by federal law, and all health care plans provided by managed health care delivery entities of any type or description, that are delivered, issued for delivery, continued or renewed in this state on or after September 1, 1997, shall provide coverage for formula **and low protein modified food products** recommended by a physician for the treatment of a patient with phenylketonuria or any inherited disease of amino and organic acids.

2. **For purposes of this section, "low protein modified food products" means foods that are specifically formulated to have less than one gram of protein per serving and are intended to be used under the direction of a physician for the dietary treatment of any inherited metabolic disease. Low protein modified food products do not include foods that are naturally low in protein.**

**3.** The health care service required by this section shall not be subject to any greater deductible or co-payment than other similar health care services provided by the policy, contract or plan.

**[**3.**]** **4.** This section shall not apply to a supplemental insurance policy, including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy, or any other supplemental policy as determined by the director of the department of insurance.

**376.1221. 1. Every health insurer and health benefit plan, as defined in section 376.1350, offering health benefit plans that are delivered, issued for delivery, continued or renewed after January 1, 2003, shall provide coverage for hearing aids that are prescribed, fitted, and dispensed by appropriately licensed professionals to dependent children through age nineteen covered under a policy, contract, or plan.**

**2. The hearing aids covered under this section shall:**

**(1) Be an electronic wearable device designed to aid or compensate for human hearing loss and any parts, attachments, or accessories, including earmolds;**

**(2) Be of a design and circuitry to optimize audibility and listening skills in the environment commonly experienced by children; and**

**(3) Have multiple-band wide dynamic range compression and direct audio input**

**compatibility.**

**3. The coverage provided by this section shall include coverage for replacement hearing aids for the child at least once every three years.**

**4. Hearing evaluations, hearing aids, prescriptions, fittings, and consumable supplies shall be reimbursed according to the contracted fee schedule. In the absence of a contracted fee schedule, reimbursement shall be at the usual and customary charges of the licensed professional. A health insurer or health benefit plan subject to this section may limit the benefit payable for hearing aids to one thousand two hundred fifty dollars for each ear with a hearing loss. An insured or enrollee who selects a hearing aid that costs more than the benefit payable pursuant to this section may pay the difference between the price of the hearing aid and the benefit payable without financial or contractual penalty to the provider of the hearing aid.**

**5. Nothing in this section shall prohibit a health insurer or health benefit plan from providing coverage that is greater than or more favorable to enrollees than the coverage provided by this section.**

**6. The health care service required by this section shall not be subject to a deductible or co-payment that exceeds twenty percent of the actual covered service costs. No health insurer or health benefit plan subject to this section shall request or require hearing acuity information from or about persons applying for coverage.**

**7. This section shall not apply to a supplemental insurance policy, including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy, short-term major medical policies of six months or less duration, or any other supplemental policy as determined by the director of the department of insurance.**

**8. The director of the department of insurance may promulgate rules to implement the provisions of this section. No rule or portion of a rule promulgated under the authority of this section shall become effective unless it has been promulgated pursuant to chapter 536, RSMo.**

**376.1253. 1. Each physician attending any patient with a newly diagnosed cancer shall provide the patient with a timely referral to an appropriate specialist within the provider network for a second opinion regarding the treatment of the patient's type of cancer. If no appropriate specialist is in the provider network, a referral shall be made to a nonnetwork specialist in accordance with this section.**

**2. Each health carrier or health benefit plan, as defined in section 376.1350, that offers or issues health benefit plans which are delivered, issued for delivery, continued or renewed in this state on or after January 1, 2003, shall provide coverage for a second**

**opinion rendered by an appropriate medical specialist when a patient with a newly diagnosed cancer is referred to such specialist by his or her attending physician. Such coverage shall be subject to the same deductible and coinsurance conditions applied to other specialist referrals and all other terms and conditions applicable to other benefits.**

**3. The provisions of this section shall not apply to a supplemental insurance policy, including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy, short-term major medical policies of six months or less duration, or any other supplemental policy as determined by the director of the department of insurance.**